

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### Pediatric Oncology Drug Development; Public Workshop

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Certifier R. LEDESMA

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the American Academy of Pediatrics (AAP), regarding pediatric oncology drug development. The public workshop is intended to provide information for and perspective from advocacy groups, interested health care providers, academia, and industry organizations on various aspects of drug development in pediatric oncology, including prioritization of new and emerging therapeutic alternatives, clinical trial design, and access to new therapeutic agents. The input from this public workshop will be used in developing topics for discussion at future meetings of the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (the subcommittee).

*Date and Time:* The public workshop will be held on Thursday, July 18, 2002, from 8 a.m. to 4 p.m.

*Location:* The public workshop will be held in the Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD 20857. Seating is limited and available only on a first-come, first-served basis. Please note there is very limited parking in the vicinity of 5630 Fishers Lane, but it is near the Twinbrook Metro station. Please bring picture identification in order to clear building security.

*Contact:* Steven I. Hirschfeld, Center for Drug Evaluation and Research (HFD-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1532, e-mail: [HIRSCHFELDS@CDER.FDA.GOV](mailto:HIRSCHFELDS@CDER.FDA.GOV).

**SUPPLEMENTARY INFORMATION:** FDA is announcing a public workshop, cosponsored with the AAP, regarding pediatric oncology drug development. On January 4, 2002, the President signed into law the Best Pharmaceuticals for Children Act (Public Law 107-109). Section 15 of the Best Pharmaceuticals for Children Act (Section 15) relates to the subcommittee.

Section 15 directs the subcommittee, in carrying out “the mission of reviewing and evaluating the data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pediatric cancers,” to:

- Evaluate and, to the extent practicable, prioritize new and emerging therapeutic alternatives available to treat pediatric cancer;
- Provide recommendations and guidance to help ensure that children with cancer have timely access to the most promising new cancer therapies; and
- Advise on ways to improve consistency in the availability of new therapeutic agents.

The agency is seeking public input to inform its future decisionmaking in regard to Section 15.

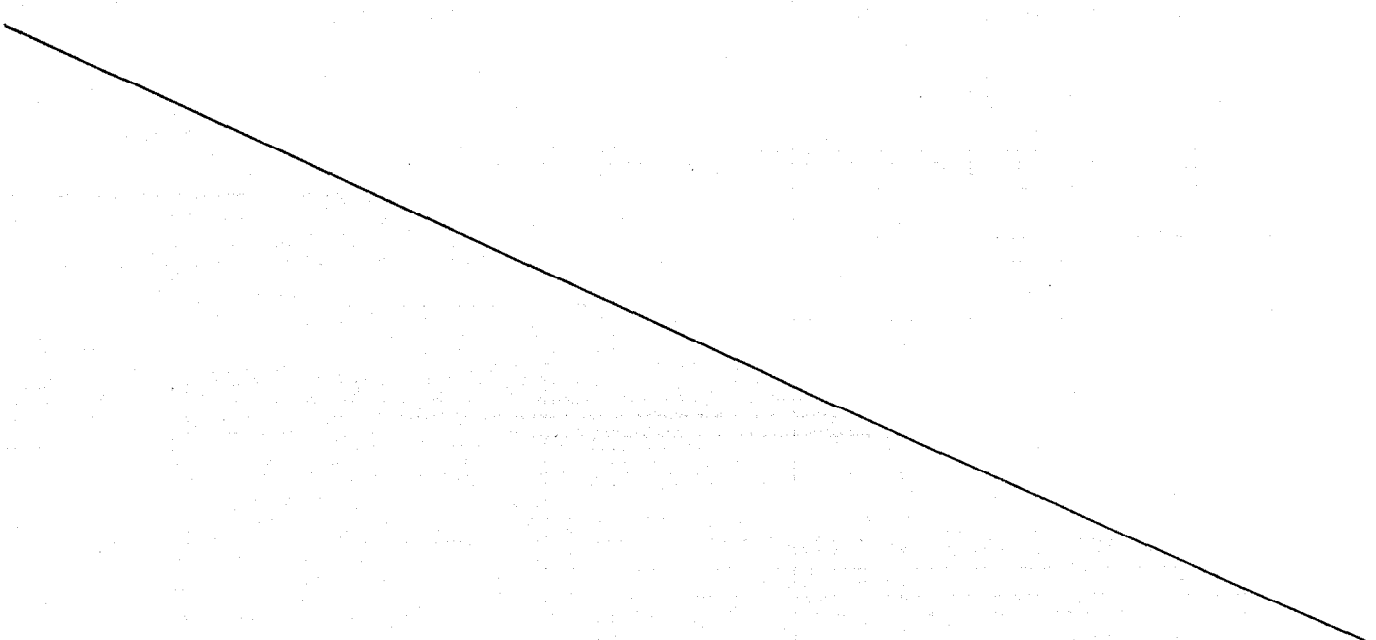
The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

*Requests to Make Oral Presentations:* The public workshop agenda allows opportunities for oral presentations from interested persons. If you desire to

make a formal oral presentation, please notify the contact person (see the *Contact* section of this document) before July 17, 2002, and provide your name, address, telephone number, fax number, e-mail address, title, business affiliation (if applicable), the sponsor of the presentation (e.g., the organization paying travel expenses or fees), a brief summary of the presentation, and the approximate amount of time requested for the presentation. Presentation times may be limited. Persons or groups having similar interests are encouraged to consolidate their presentations and present them through a single representative.

Persons needing a sign language interpreter or other special accommodations should notify the contact person by July 17, 2002.

*Transcripts:* Transcripts of the public workshop will be available for review at the Dockets Management Branch Public Reading Room, Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852 and on the Internet at <http://www.fda.gov/ohrms/dockets/ac/cder02.htm> or you may request a transcript of the public workshop from the Freedom of



Information Staff (HF1-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 20 working days after the public workshop, at a cost of 10 cents per page.

Dated: July 8, 2002  
July 8, 2002.

*Margaret M. Dotzel*

Margaret M. Dotzel,  
Associate Commissioner for Policy.

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*Regina Sedano*